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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,896	12/11/2001	Xuanchuan Yu	LEX-0280-USA	2399
24231	7590	10/03/2003	EXAMINER	
LEXICON GENETICS INCORPORATED 8800 TECHNOLOGY FOREST PLACE THE WOODLANDS, TX 77381-1160			MOORE, WILLIAM W	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/014,896

Applicant(s)

YU ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

While two Groups of claims had been defined for restriction under 35 U.S.C. §121, and Group 1, claims 1-3, had been provisionally elected a telephone conversation with Mr. David W. Hibler on June 25, 2003, a search of the prior art identified documents relevant to all four claims present in the application thus the requirement for restriction is hereby VACATED and claims 1-4 are examined together herein.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility.

A claimed invention must possess a specific, substantial and credible *in vitro* or *in vivo* utility, but the instant application cannot identify any specific, substantial, utility for the invention described by the claims known to the inventors at the time the application was filed. It is agreed that the polypeptides having the amino acid sequences of SEQ IDs NOs:2 and 4 share a significant degree of amino acid sequence homology with other, prior art, human metalloproteases. Yet the polynucleotides described by claims 1-4 lack utility because the specification discloses no specific *in vitro* utility for an isolated nucleic acid sequence having the nucleotide sequence of SEQ ID NO:1, nor any disclosure of a specific *in vitro* utility for isolated nucleic acids having generic nucleotide sequences that encode the amino acid sequences of SEQ IDs NOs:2 and 4. Neither does the specification indicate any specific *in vivo* utility for nucleic acids encoding the amino acid sequences of SEQ IDs NOs:2 and 4. While the specification proposes, at page 1, that "disclosed polynucleotides . . . can be used for diagnosis, drug screening, clinical trial monitoring, the treatment of diseases and disorders, and cosmetic or nutraceutical applications" these proposed utilities

are not specific because there is no disclosure of any specific disease state or medical condition may or may not be diagnosed or treated, how to screen for drugs that affect any specific function or physiological conditions, any specific nature of clinical trials to be monitored for any particular purpose, and no disclosure of the specific nature of any cosmetic or nutraceutical applications.

Although Applicant proposes, at pages 2 and 3, that the physiological function of the encoded products might be determined by constructing transgenic animals deficient in the expression of nucleic acid sequences encoding the amino acid sequences of either of SEQ IDs NOs:2 or 4, the specification discloses no specific physiological condition or state that implicates the lack of function, or the aberrant function, of either protease encoded by SEQ ID NO:1, and provides no suggestion of a physiological or cellular function for either native protease encoded by a claimed nucleic acid sequence. A method of use of a material for further research to determine, e.g., its specific biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). Mere allegations of a prospective, potential, utility cannot rise to the level of a credible assertion of a specific in vivo utility that is substantial. Indeed, the specification's diffuse assertions indicate the contrary, that Applicant knew no specific utility for either native polypeptide encoded by claimed nucleic acid sequences at the time the application was filed that would permit an immediate use by the public of a disclosed nucleic acid sequence, or any use by the public of an expression vector or cell comprising a disclosed nucleic acid sequence.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

#### *Conclusion*

Claims 1-4 present no issues of enablement as to making, or of an indefinite description, under the first paragraph and second paragraphs of 35 U.S.C. §112 because the scope of the intended subject matter is clear and the artisan can make both the specific polynucleotide of claims 1 and every member of the genera of isocoding polynucleotides specifying amino acid sequences of SEQ IDs NOs:2 and 4 of claims 2-4. Polynucleotides products described by claims 1-4 are also free of the prior art made of record with Applicant's Information Disclosure Statement filed March 12, 2002, as well as the two PCT publications made of record herewith, Plowman et al., WO 01/83782, and Shimkets et al., WO 00/58473. Due to the excessive size of the publication of Shimkets et al., a copy is not supplied with this communication but the GenEmbl database entry for the pertinent disclosure of the human ORFX sequence of SEQ ID NO:218 of Shimkets et al., AAB40345, accompanies this communication.

Plowman et al. disclose, in the paragraph spanning pages 161-162 and their SEQ IDs NOs: 34 and 69, respectively, the nucleic acid sequence encoding, and the encoded 473-amino acid sequence of, a human metalloprotease that differs at but one amino acid position, position 84 where an arginine is present rather than the histidine at this position in SEQ ID NO:2 but is otherwise identical to SEQ ID NO:2 herein from position 1 through position 300, inclusive, but diverges and is non-identical thereafter. The encoded amino acid sequence of SEQ ID NO:69 of Plowman et al. also differs at but one amino acid position, position 84 where an arginine is present rather than the histidine at this


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position in SEQ ID NO:4, but is otherwise identical to SEQ ID NO:4 herein from position 1 through position 325, inclusive, but diverges and is non-identical thereafter. Thus the nucleic acid sequence encoding the truncated metalloprotease amino acid sequence of SEQ ID NO:69 of Plowman et al. can neither disclose nor suggest the subject matters of claims 1-4 herein.

Neither can the disclosure of a nucleic acid sequence encoding the fragment of a metalloprotease amino acid sequence of SEQ ID NO:218 of Shimkets et al. disclose or suggest the subject matters of claims 1-4 herein. This is because, while the 166 amino acid sequence of SEQ ID NO:218 of Shimkets et al. differs at but one position, position 107 where a tryptophan is present rather than the arginine at this position – position 153 – in both of SEQ IDs NOs:2 and 4 herein, the sequence of Shimkets et al. is otherwise identical to the amino acid sequences of SEQ IDs NOs:2 and 4 herein from position 48 through position 212, inclusive, of both and but diverges and is non-identical thereafter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. The examiner's direct fax phone number is 703.746.3169. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore  
September 30, 2003



NASHAAT T. NASHED PH.D.  
PRIMARY EXAMINER